

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:

James D. Jacobson

Serial No. 09/457,173

Filed: December 8, 1999

Group Art No.: 1723

Examiner: Sun U. Kim

For:

MICROPOROUS FILTER MEMBRANE

METHOD OF MAKING

MICROPOROUS FILTER MEMBRANE

AND SEPARATOR EMPLOYING

MICROPOROUS FILTER MEMBRANES

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# APPELLANT'S BRIEF UNDER 37 C.F.R. § 1.192

Dear Sir:

# (1) REAL PARTY IN INTEREST

The real party in interest in this appeal is Baxter International Inc., assignee of the invention claimed in the present application, which assignment is recorded in the United States Patent and Trademark Office at Reel/Frame: 10471/0913.

### (2) RELATED APPEALS AND INTERFERENCES

None.

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## (3) STATUS OF CLAIMS

Applicant originally filed Claims 1-102. In response to a restriction requirement under 35 U.S.C. 121, Applicant elected to prosecute Claims 1-5, 14-30 and 102. Claims 1-5, 14-30 and 102 are pending and all stand rejected. Claims 6-13 and 31-101 were withdrawn from consideration by the Examiner and are not appealed.

### (4) STATUS OF AMENDMENTS

No Amendments have been made subsequent to the Final Rejection mailed February 4, 2003.

# (5) SUMMARY OF THE INVENTION

The present invention, as set forth in the claims on appeal, is directed to a monolithic polymeric filter membrane having a polymeric filter layer and a polymeric support layer. The polymeric filter layer includes micron-scaled precision-shaped pores, and the polymeric support layer includes a precision-shaped porous support structure for the filter layer.

As set forth in the claims on appeal, the polymeric filter membrane is "monolithic," meaning that there is no discernible line of distinction between the filter and the support layers, (See the cross-section view of the membrane in Figures 4 and 12g). For example, the filter membrane may comprise a filter layer and a support layer that are formed from a common

material, such as a single starting polymeric film, in which case there is no discernible line of distinction because the starting structure is itself a common structure, such as a single layer or sheet. Alternatively, the filter and support layers may each be fashioned from separate films, for example, which are joined together in an uncured or a partially cured state so that when fully cured, the layers chemically bond to form the final product free of a discernible line of distinction between the layers.

# (6) ISSUES

- (A) Whether the subject matter of Claims 1-5, 14-18, 21-30 and 102 would have been obvious to a person of ordinary skill over U.S. Patent No. 5,753,014 to Van Rijn, in view of U.S. Patents No. 6,264,044 to Meyering or 5,275,725 to Ishii.
- (B) Whether the subject matter of Claims 19-20 would have been obvious over <u>Van Rijn</u> in view of <u>Meyering</u> or <u>Ishii</u> and further in view of U.S. Patent No. 5,807,406 to <u>Brauker</u>.

# (7) GROUPING OF CLAIMS

Claims 1-5, 14, 16-30, and 102 stand or fall together.

Claim 15 stands or falls separately from the above claims.

# (8) ARGUMENT

# I. CLAIMS 1-5, 14, 16-18, 21-30 AND 102 WOULD NOT HAVE BEEN OBVIOUS OVER VAN RIJN IN VIEW OF MEYERING OR ISHII.

The Examiner rejected 1-5, 14, 16-18, 21-30 and 102 under 35 U.S.C. § 103(a) as being obvious over Van Rijn in view of Meyering or Ishii. As described in more detail below, Van Rijn, Meyering, and Ishii do not describe, teach, or suggest a "monolithic" polymeric filter membrane as required by the pending claims. There is no prima facie showing of obviousness or, alternatively, any such purported showing is fully rebutted herein.

First, it should be noted that "monolithic" is a term that is specifically defined in the present application. The Examiner has acknowledged that Van Rijn does not teach a "monolithic" filter membrane, and it is respectfully submitted that a "monolithic" filter membrane is not shown or suggested in the Meyering and Ishii patents as alleged by the Examiner.

Furthermore, it is respectfully submitted that the pending claims would not have been obvious to someone skilled in the art based on a combination of the <u>Van Rijn</u> patent and <u>Meyering</u> or <u>Ishii. Van Rijn</u> teaches a membrane filter having <u>separate</u> and <u>distinct</u> (not "monolithic") support and filter layers. The <u>Meyering</u> patent discloses a random-fiber or depth-filter type membrane in which particles are captured in the interstices of

Material or in a labyrinth of fibers formed within the membrane.

Ishii patent also discloses a random-fiber membrane, and is specifically directed toward a flat woven/non-woven filter laminate that has sufficient strength to withstand back flushing. Neither Meyering nor Ishii teaches or suggests any aspect of the claims under appeal -- i.e. they do not teach or suggest (1) a polymeric filter layer with micron-scaled precision-shaped pores, (2) a precision-shaped support structure, or (3) the "monolithic" combination of the two.

# A. "Monolithic" in the Claimed Subject Matter is Far Different from what is Shown in Meyering or Ishii.

"Monolithic" is specifically and consistently defined in the present application -- it requires that there be "no discernible line of distinction between the filter and support layers" (page 23, line 17-19 See the cross-sectional views of the membrane in Figures 4 and 12g). This definition is consistently used in the specification, and it encompasses for example, (1) a membrane in which the filter and support are made from the single original sheet or film or (2) a membrane in which the filter and support begin as different films that are cured together to form chemical bonds or cross-links that result in a filter membrane product with no discernible line of distinction between the filter and support layers.

For example, on page 16 at lines 12-15, it is indicated that the monolithic filter and support layer of the membrane filter "may be formed from a single polymeric film or from different films that are joined together to form a monolithic filter membrane." This is followed at line 26 with the statement: "the filter membrane may be made monolithic by forming the filter and support layers from a single film or from separate films of the same or sufficiently compatible materials to allow the layers to become monolithic when bonded together."

The specification describes in detail how two or more layers may be joined to form a "monolithic" filter membrane.

Page 21, line 32 states, "To form the monolithic filter membrane, the first and second polyimide layers, which are not fully cured, are cured together to remove any interface therebetween and create the monolithic filter membrane, which is then removed from the silicon wafer or other substrate" [emphasis added]. Additionally, the specification describes that the final curing of the compatible polymeric layers may cause cross-links or chemical bonds to form between the layers. As a result of this, "any lines of distinction between the layers disappear, and a monolithic filter membrane is formed as best seen in Figure 12g" (Page 36, lines 10-23).

Consequently, a "monolithic" membrane of the present invention is one in which the filter and support layers have no

discernible line of distinction between them. This "monolithic" membrane can be formed, for example, from a common material such as a single original sheet or it can be formed from separate sheets or layers which are of the same or of sufficiently compatible materials that when joined they chemically bond or cross-link to form a single "monolithic" filter membrane with no discernible line of distinction to the observer.

# B. <u>Van Rijn</u> Does Not Describe or Suggest the Claimed "Monolithic" Filter Membrane.

The <u>Van Rijn</u> patent, whether considered alone or in combination with <u>Meyering</u> or <u>Ishii</u>, does not teach, suggest, or disclose a "monolithic" filter membrane having at least a polymeric filter layer and a polymeric support layer. Applicant agrees with the Examiner that <u>Van Rijn</u> generally discloses a membrane filter having a membrane made of a polymeric material, which is one of many materials proposed, and a separate support made of organic or inorganic material, also selected from a long list of varied materials (identified in column 3, lines 50-62), ranging from steel or iron alloys to polyamide, polypropylene, polyolefin and other materials.

However, unlike <u>Van Rijn</u>, the pending claims of the present invention require a polymeric filter membrane and support that are "monolithic" as defined above. Rather than teaching a

"monolithic" filter, Van Rijn suggests the importance of separate layers. Van Rijn teaches that the filter membrane may be formed from organic or inorganic material, such as ceramic, metal, or metal alloys, or from polymeric material such as polyurethane, polyterafluorethylene or polyamide (Col. 2, lines 63 - col. 3, lines 23), and that the support layer may be created from an inorganic material such as silicon, steel, iron alloys, or other materials such as polyamide, polyvinyl, polypropylene and others (Col. 3 lines 50-62). Although Van Rijn suggests that the support and membrane are created from equivalent materials with the same or similar components for the preferred embodiment (Col. 4, lines 38-44), this does not amount to a teaching or suggestion that the components form a "monolithic" polymeric membrane filter as described in the pending claims.

It is clear from such a varied list of disparate materials that <u>Van Rijn</u> did not conceive, nor does he suggest, that the separate layers in filter membrane could be "monolithic," as required by the claims of the present invention. On the contrary, <u>Van Rijn</u> emphasizes the separate nature of the layers in his patent and points out that an intermediate layer may be deposited for bonding enhancement and stress reduction between the distinct and separate layers. <u>Van Rijn</u> states that "between the membrane layer and support layer an intermediate layer may

be deposited for bonding enhancement and stress reduction consisting of, e.g. Borax, chromium, nickel, titanium, silicon oxide or phosphorous pentoxide" (Col. 3, lines 45-48). Van Rijn even suggests that the intermediate layer could act as a etch stop layer (Col. 3 lines 49-50).

As recognized by the Examiner in his Final Office Action,

Van Rijn does not teach, describe, or suggest a "monolithic"

filter membrane as required by the present claims. ("Claims 1-5,

14-18, 21-30 and 102 essentially differ from the membrane filter

of Van Rijn in reciting that the membrane is monolithic.")

Moreover, Van Rijn teaches away from the present invention by

stressing the separate nature of the filter and support layers.

For the above reasons, it is respectfully submitted that the

claimed subject matter is not rendered obvious by the Van Rijn

patent.

# C. <u>Ishii</u> Does Not Teach or Suggest a "Monolithic" Membrane.

Unlike the present invention, <u>Ishii</u> describes a flat woven/non-woven industrial filter laminate that has sufficient strength to withstand back-flushing to clear the filter of particulate or other suspended material (Col. 6, lines 35-44).

<u>Ishii's</u> "flat separation membrane leaf" has a flat membrane that includes an inner <u>woven</u> coarse layer with large voids and <u>non-</u>woven layers (made of densely arranged fibers) partially adhered

to the inner layer by adhesive or heat fusing. A liquid polymer layer is then applied to the surface of the non-woven layers.

Whereas the present invention is directed to a "monolithic" membrane created, for example, from either a single layer or the chemical bonding of two or more partially-cured layers to form a seamless membrane, the <u>Ishii</u> patent describes preformed or cured layers that are brought together and then fused or bonded together. The resulting filter in the <u>Ishii</u> is quite different from the present invention because in cross-section the filter in <u>Ishii</u> would clearly have a discernible seam or other line of distinction between the inner woven core and a non-woven fiber mat layers, regardless of whether the layers are adhesively bonded or heat fused. When these two very different materials are brought together, they would clearly form an observable line where one material ends and the other begins.

Further, <u>Ishii</u> presents a multi-layer industrial filter structure, with interwoven and non-interwoven mats. In these types of filters, the filter operates by capturing particles in the interstices of the interwoven or non-interwoven material or in a labyrinth of fibers formed within the membrane. <u>Ishii</u> describes a membrane that does not employ precision-shaped pores in either a filter layer or support layer, but rather uses a woven fiber core and non-woven fibrous layers to support the

semi-permeable membrane. The construction and operation of the filter described in <u>Ishii</u> is a fundamentally different from the precision-shaped micron-scaled filter membrane of the present invention, which is particularly suited for filtering biological suspensions.

Consequently, the <u>Ishii</u> patent does not teach, suggest, or disclose a "monolithic" membrane having a filter layer with micron-scale, precision-shaped pores or a precision-shaped support structure, which would appear to have been fashioned from a single sheet or membrane. For these reasons, it is submitted that the pending claims would not have been obvious to a person of ordinary skill in view of <u>Ishii</u>.

# D. The <u>Meyering</u> Patent Does Not Teach, Suggest or Demonstrate A "Monolithic" Filter

Meyering patent is comparable to the previously cited and discussed <u>Ishii</u> patent and is fundamentally different from the present application. <u>Meyering</u>, like <u>Ishii</u>, discloses a random filter or a depth-filter. The size and shapes of the pores in any given section of the filter is a consequence of the filter structure and the random arrangement of the fibers. In contrast to the present invention, <u>Meyering</u> does not disclose and is not

directed to a polymeric filter membrane having a filter layer that includes micron-scale precision-shaped pores.

Furthermore, the support structures defined in <a href="Meyering">Meyering</a> are fundamentally different. First, <a href="Meyering">Meyering</a> discloses a process in which doping materials 26, 28, and 36 are layered onto and "impregnate" a support material 12 (Col. 11 line 5 - Col. 5 line 3). Second, the fusion of the filter to a filter housing, as described in <a href="Meyering">Meyering</a>, creates a fundamentally different apparatus than the "monolithic" membrane described in the pending claims. The filter housing, as described in the <a href="Meyering">Meyering</a> specification, is not bonded in such a way as to leave no discernible line or seam between the filter housing and the filter (Col. 13 line 59 - Col. 14 line 23).

Even though the Meyering patent uses the term "monolithic," it is respectfully submitted that the Examiner incorrectly construed the use of "monolithic" in Meyering. In the Meyering patent, the word "monolithic" is used in accordance with its ordinary definition: i.e. "constituting or acting as a single, rigid, unified whole." In the present application, the term "monolithic" refers to that characteristic of the claimed membrane in which there is no readily visible line of distinction between the micron-scale precision-shaped pore filter layer and the precision-shaped porous support structure, as seen, for example, in the cross-sectional views of Figures 4

and 12g. Nowhere in the <u>Meyering</u> patent does it suggest that the bond between the filter housing and the filter leaves no discernible line of distinction. The <u>Meyering</u> patent simply uses the term "monolithic" to describe how the resulting filter is unified and rigid.

It is respectfully submitted that no one skilled in the art following the teaching of the Meyering patent would or could make the claimed invention, because the teaching of the Meyering is directed to a fundamentally different kind of filter structure. Although the Meyering patent results in a filter membrane that is a single, rigid unit, it is not a "monolithic" membrane as set forth in the pending claims, and Meyering does not teach or suggest such a membrane.

E. The Rejection of Claims 1-5, 14, 16-18, 21-30 and 102 as Unpatentable over Van Rijn in View of Meyering or Ishii Is Erroneous Because There is No Suggestion, Motivation or Teaching to Combine these References.

As discussed in the Summary of the Invention above, the present invention is directed to a "monolithic" polymeric filter membrane, which has micron-scaled, precision-shaped pores and a precision-shaped support structure for the filter layer. The Examiner relied upon Van Rijn in view of Meyering or Ishii to reject claims 1-5, 14, 16-18, 21-30 and 102 for obviousness. As described in detail above, both Meyering and Ishii are directed

toward fundamentally different filter structures and entirely different filtration principles than disclosed in the pending application.

The Examiner previously recognized that the Van Rijn patent does not teach a "monolithic filter" as required by the pending application. However, the Examiner cites Meyering and Ishii as demonstrating that "It would have been obvious to a person of ordinary skill in the art to fuse polymeric membrane into a polymeric support to form an integrated membrane (i.e. monolithic membrane)." It is respectfully submitted that the Examiner improperly confuses the properties of an integrated membrane and a membrane that is "monolithic" as required by the pending claims. The definition of "integrate" is to join or bring together with something else. Consequently, a "monolithic" membrane may be an integrated membrane, but an integrated membrane is not necessarily "monolithic" as required Ishii, Meyering and Van Rijn all may show an by the claims. integrated membrane, yet none is "monolithic" as defined in the present application.

Furthermore, when an obviousness determination is based on multiple prior art references, there must be a "clear and particular" showing of some "teaching, suggestion or reason" to combine the references. <u>In re Dembiczak</u> 175 F.3d 994, 1000, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). There is no teaching or

suggestion in <u>Van Rijn</u> of a "monolithic" membrane and there is no teaching or suggestion in <u>Meyering</u> or <u>Ishii</u> of "monolithic" membranes that have no discernible line of distinction or seam between the filter layer and the support layer. The mere fact that the <u>Van Rijn</u> may be modified in the manner suggested by the Examiner does not make the modification obvious. <u>Van Rijn</u> and the prior art do <u>not</u> suggest the desirability of the modification, and the only suggestion for the claimed subject matter is found in the present application. <u>See In re Fitch</u> 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992).

An invention is not obvious solely because it is made up of two or more elements contained in separate references or patents — and in the present situation it is respectfully submitted that the elements of the claimed invention are not even found separately in the cited prior art. Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1575, 1 U.S.P.Q.2d 1593, 1602 (Fed. Cir. 1987). The requirements of a clear and particular showing of the suggestion to combine is grounded in the fear that all patents may be declared invalid merely upon finding similar elements in separate references. In re Dembiczak, 175 F.3d at 999, 50 U.S.P.Q.2d at 1617. Close adherence to the requirement of some objective teaching leading to the combination is especially import in the case of a less technologically complex invention since the very ease with which the invention can be

w.L. Gore & Assoc. Inc. v. Garlock, Inc., 721 F.2d 1540, 1553,
220 U.S.P.Q. 303, 313 (Fed. Cir. 1983).

With all due respect, it is submitted that it is only with the knowledge of the claimed subject matter of the present invention, that the Examiner has the incentive to attempt to make a "monolithic" filter membrane. However, the Federal Circuit has made clear, that the teaching of the present application may not be used against the teacher for the purpose of combining references that otherwise would not, in any event, be logically combinable. In re Fine 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988). Indeed, even with the disclosure of the present application it is not apparent how the teachings of Ishii or Meyering could be combined with Van Rijn to reach the claimed "monolithic" filter membrane

As set forth above the <u>Van Rijn</u>, <u>Meyering</u> and <u>Ishii</u> are directed to fundamentally different structures and filtration methods. Despite whether it is logical to combine these references, the combination would not, in any event, result in the claimed subject matter. <u>Ishii</u> discloses adhesive or heat fusing two preformed layers of fundamentally different construction -- a coarse woven core and fibrous mat layers. If the <u>Ishii</u> idea of adhesive or heat fusing two layers were applied to Van Rijn, the apparent result would be, at most,

separately formed and cured filter and support layers, adhesively or heat fused with a visible line of distinction between them (which is little different from the disclosure in <a href="Van Rijn">Van Rijn</a> itself). What is clear is that the claimed invention would not result of such a combination.

Unlike <u>Ishii</u>, <u>Meyering</u> also discloses a process in which doping materials 26, 28, and 36 are layered onto and "impregnate" a support material 12 (See discussion at Co. 11, line 5 - Col. 12, line 3 of the <u>Meyering</u> patent and Fig. 2). It is respectfully submitted, however, that such a process has no reasonable combinability with the structure or process shown in the <u>Van Rijn</u> patent to reach the claimed invention.

Impregnation of a support material with doping material does not

lead one toward the claim invention but, indeed, away from it.

As a result, it is respectfully submitted that the claimed subject matter is not disclosed or suggested by the cited Meyering, Ishii, and Van Rijn patents. In addition, it is respectfully submitted that it would not have been obvious to a person of ordinary skill to combine the fundamentally different Meyering, Ishii, and Van Rijn patents in a manner to yield the present invention as described in the pending claims. For these reasons, it is submitted that a prima facie case for obviousness is not made or is rebutted, and it is requested that the

rejection in the Final Office Action of February 4, 2003 be reversed.

# II. CLAIM 15 WOULD NOT HAVE BEEN OBVIOUS OVER VAN RIJN, IN VIEW OF ISHII, OR MEYRING.

Claim 15 is directed to a "monolithic" polymeric filter comprised of a polymeric filter layer with micron-scale precision-shaped pores and a precision-shaped support layer that are defined on opposite sides of a single film. A "monolithic" polymeric filter that is constructed from a single original film is fundamentally different from multi-layer filters of the prior art. For this additional reason, Applicant respectfully requests that the Board separately consider the Examiner's rejection of this claim.

The Examiner rejected claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Van Rijn in view of Meyering or Ishii.

All of these patents are directed toward multi-layered filter designs and do not teach, suggest or disclose any type of filter formed from a single polymeric sheet or film. Applicant hereby respectfully submits that a membrane filter comprising of a support layer and filter layer as recited in claim 15, which are defined on the opposite layers of a single film, would not have been obvious to one skilled in the art based on the teachings of Van Rijn in view of Meyering or Ishii.

The reasons set forth above for reversing the Examiner's rejection of claims 1-5, 14-18, 21-30 and 102 in view of Van Rijn in view of Meyering or Ishii apply as well to claim 15 and are not restated here. Claim 15, however, is patentable over Van Rijn, Meyering and Ishii for additional reasons.

The <u>Van Rijn</u> patent consistently describes the filter and support layers as being separate and distinct entities. It lists both organic and inorganic materials, which could possibly be brought together to form the membrane. From the descriptions of the support layer, filter layer, and the possible intermediate layer between the two, <u>Van Rijn</u> did not conceive, and certainly did not suggest, that a membrane filter could be created with the filter and support layers on opposite sides of the same film. In fact, the <u>Van Rijn</u> patent tends to lead the reader away from a single film design.

The <u>Ishii</u> patent is directed to flat woven/non-woven filter laminate. Unlike the single film construction described in claim 15, <u>Ishii</u> describes a filter constructed from separated preformed and cured layers that are brought together and then heat fused or adhesively bonded. There is simply no teaching or suggestion in the <u>Ishii</u> reference that would logically lead one to combine the features of that device with the filter of <u>Van</u>

<u>Rijn</u> to reach a membrane filter as described in claim 15. Both patents focus on multi-layered designs, and therefore, would

have the propensity to lead the reader away from a single film design.

Meyering also discloses a random fiber or depth-filter type membrane in which the particles are captured in the interstices of material or in a labyrinth of fibers formed with the membrane. The filter member is constructed by impregnating doping materials 26, 28 and 36 into a support material 12 (See Col. 11 Line 5 - Col. 12 line 3). Once the filter membrane is formed, the filter is heat bonded to the filter house (Col. 13 64 - Col. 14 line 13). Consequently, Meyering does not disclose, suggest, or teach that a filter membrane having a support layer and a filter layer could be constructed from a single film.

The single film construction of a membrane filter of the claimed construction is fundamentally different from the multi-layered filters and complete filter structures that were the result of heat fusing or adhesive bonding process. It is respectfully submitted that one of ordinary skill in the filtration field would not view the filter structures or teachings of Meyering or Ishii patents as being helpful, instructive, or relevant to the claimed single film construction. Additionally, the filter structures or teachings of Meyering or Ishii patents teach nothing to one of ordinary skill as to how to make a filter structure of Van Rijn in from a

single sheet or film as described in claim 15. For these added reasons, Applicant respectfully submits that the Examiner has not presented evidence establishing a prima facie case of obviousness and requests that the rejection of claim 15 in the Final Office Action of February 4, 2003 be reversed.

# III. CLAIMS 19-20 WOULD NOT HAVE BEEN OBVIOUS OVER VAN RIJN IN VIEW OF MEYERING OR ISHII AND FURTHER IN VIEW OF BRAUKER

The Examiner rejected claims 19-20 under 35 U.S.C. § 103(a) as being unpatentable over <u>Van Rijn</u> in view of <u>Meyering</u> or <u>Ishii</u> as applied to claim 1 above, and further in view of U.S. Patent No. 5,807,406, hereafter referred to as <u>Brauker</u>. The issue of obviousness with respect to claim 1 is addressed in Section I. of this brief and the reasons set forth therein for reversing the Examiner's rejection fully apply here. In addition, it is respectively submitted that it is illogical and non-obvious to combine the features of Van Rijn and Brauker.

Two criteria have emerged for determining whether prior art is analogous: 1) whether the art is from the same field of endeavor, without regard to the problem addressed, and 2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. In re<br/>
Clay 966 F.2d 656, 658, 23 U.S.P.Q.2d 1058, 1060 (Fed. Cir. 1992).

The Examiner found that <u>Brauker</u> was within the field of the applicant's invention because "<u>Brauker</u> teaches a porous microfabricated polymer membrane structure made of etchable or photosensitive polyimide." Although both the present invention and <u>Brauker</u> technically concern membranes in the broadest sense of the word, the Examiner has failed to take into account that "membrane" refers to many different devices, and that not all "membranes" are filters as described in the present claims.

Brauker discloses a device that, once implanted in the host tissue, promotes the formation of vascular structure (Col. 2 line 7 - Col. 8 Line 25). The Brauker patent is specifically directed to tissue growth structures that are implanted to promote a biological response by the formation of vascular structures near the host tissue interface. No liquid or other material passes through the structure -- there is no filtration form, function, or feature disclosed in Brauker. Therefore, the field of endeavor which encompasses Brauker is the field of implanting materials into body tissue, and in a more specific sense, to implanting materials that have a therapeutic effect (Col. 1 lines 5-11).

In contrast, Applicant's field of endeavor in a general sense is the field of microporous filter membranes, and in a more relevant sense is the field of polymeric microporous filter membranes of the type employing a filter layer with micron-

scaled precision-shaped pores and a precision-shaped support structure. The present invention is a filter, whereas <u>Brauker</u> describes an implantable lattice structure that is designed to promote the growth of living cells.

Since the <u>Brauker</u> reference is not within Applicant's field of endeavor, the only other way it can be properly combined with the other references in an obviousness rejection is if it is reasonably pertinent to the problem Applicant attempts to solve.

Id. A reference is reasonably pertinent only if it logically would have attracted the inventor's attention in solving his problem, and therefore, the purpose of the present invention and the purpose of the <u>Brauker</u> reference are determining factors.

Id. at 659.

The purpose of the <u>Brauker</u> is to create a device that provides an implantable lattice structure, which is designed to hold living cells, to enhance tissue growth and to have a therapeutic effect once implanted into human tissue. In contrast, the purpose of the Applicant's invention is to develop a microporous membrane filter for the filtration of micronscaled particulate. The problem faced in <u>Brauker</u> is the creation of specific microarchitectures that would promote the growth of vascular structures in the surrounding body tissue. This problem is not remotely pertinent, except with improper hindsight, to the problems the Applicant has solved. A person

having ordinary skill in the art would not have been attracted to a reference dealing with implanting materials into body tissue to solve the problem of creating an efficient microporous "monolithic" membrane filter.

Therefore, the Examiner clearly erred in combining <u>Brauker</u> with <u>Van Rijn</u> in the obviousness rejection. For these additional reasons, it is respectfully submitted that there is no <u>prima facie</u> case of obviousness and that the rejection of claims 19-20 was improper and should be reversed.

### CONCLUSION

For the reasons set forth above, Applicant respectfully submits that Claim 1-5, 14, 16-30 and 102 are allowable, that the Examiner has not established a prima facie showing of obviousness, and that the decision of the Examiner rejecting these claims should be reversed. Applicant also submits that no showing of obvious has been made with respect to Claim 15, which stands separately from the other claims, and that the Examiner's rejection of this claim also should be reversed.

Respectfully submitted,

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# (9) APPENDIX 1. A monolithic polymeric filter membrane comprising: (a) a polymeric filter layer including micron-scale precision-shaped pores and (b) a polymeric support layer including a precision-shaped porous support structure for the filter layer. 2. The filter membrane of claim 1 in which the support layer is thicker than the filter. 3. The filter membrane of claim 2 in which the support layer is thicker than the filter layer by a factor of between 2 and 250.

- 4. The filter membrane of claim 2 in which the support layer is substantially coextensive with the filter layer
- 5. The filter membrane of claim 1 in which the support layer includes at least two sublayers, a first sublayer of a selected porosity and a second sublayer of different porosity than the first sublayer and disposed between the first sublayer and the filter layer.
- 14. The filter membrane of claim 1 in which the filter and support layer are comprised of different materials that are sufficiently compatible to form a monolithic membrane.
- 15. The filter membrane of claim 1 in which the filter and support layer are defined on opposite sides of a single film,

the pores communicating with the porous support structure to allow the passage of filtrate therethrough.

- 16. The filter membrane of claim 1 in which the filter and support layer are formed separately of the same material and joined together to form the monolithic membrane.
- 17. The filter membrane of claim 1 in which the polymeric material of the filter layer is photosensitive, etchable, or suitable for laser ablation or x-ray treatment, and the polymeric material of the support layer is photosensitive, etchable or suitable for laser ablation or x-ray treatment.
- 18. The filter membrane of claim 1 in which the polymeric material of the filter layer is etchable, and the polymeric material of the support layer is photosensitive or suitable for laser ablation.
- 19. The filter membrane of claim 1 in which the polymeric material of the filter layer and support layer is an etchable polyimide material.
- 20. The filter membrane of claim 1 in which the polymeric material of the filter layer and the support layer comprises photosensitive polyimide material.
- 21. The filter membrane of claim 1 in which the filter membrane is flexible.

22. The filter membrane of claim 21 in which the filter membrane is sufficiently flexible to be disposed along a radius of curvature of at least one-half inch. 23. The filter membrane of claim 1 in which the pore size is less than or equal to about 20 microns. 24. The filter membrane of claim 1 in which the pore size is less than or equal to about 0.65 microns. 25. The filter membrane of claim 1 in which the pore size is less than or equal to about 0.22 microns. 26. The filter membrane of claim 1 in which the pore size is less than or equal to about 2 microns. 27. The filter membrane of claim 1 in which the pore size is less than or equal to about 0.08 microns. 28. The filter membrane of claim 1 in which said micronscale precision-shaped pores are non-circular. 29. The filter membrane of claim 1 in which said pores are elongated. 30. The filter membrane of claim 28 in which the pores are sized and shaped to prevent the passage of human white blood cells and permit the passage of red cells and platelets. 102. The filter membrane of claim 1 in which the pore size is less than or equal to about 0.45 microns. - 27 -